PATENT

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant(s):

Klaus ABRAHAM-FUCHS et al.

Int'l Application No.:

PCT/EP2005/050517

Application No.:

NEW

Filed:

August 16, 2006

For:

METHOD FOR CONDUCTING A CLINICAL STUDY

INFORMATION DISCLOSURE STATEMENT (SUBMISSION CONCURRENT WITH THE FILING OF A NEW PATENT APPLICATION)

Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314 Mail Stop PCT

August 16, 2006

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications, or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. <u>COPIES</u>

Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each
publication or that portion which caused it to be listed; and (iii) all other information
or that portion which caused it to be listed.

This application is a National Phase of a PCT application. Some or all of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should be forwarded from the International Search Authority. If copies are needed, please contact the undersigned.

10/589535 IAP11 Rec'd PCT/PTO 16 AUG 2006

New PCT National Phase Application Docket No. 32860-001079/US

Because the present application is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

a. DOCUMENTS IN THE ENGLISH LANGUAGE

Some of the attached patents, publications, or other information in the English language do not require a statement of relevancy.

b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

Many of the documents have been discussed in the PCT Search Report, the PCT Preliminary Examination Report, and/or throughout the specification. The PCT Search Report and PCT Preliminary Examination Report, along with a German translation aid translating key terms into English, indicate the degree of relevance found by the PCT Office, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

c. ENGLISH LANGUAGE SEARCH REPORT

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

d. **OTHER**

The following additional information is provided for the Examiner's consideration.

Applicants include a German translation aid for translating terminology in the PCT Search Report and Examination Report to thereby satisfy Applicant's requirement for an English language translation thereof. European Patent Publication 0936566 corresponds to U.S. Patent 6,839,566. Further, applicant encloses a copy of the German Office Action issued May 5, 2006 for German Patent Publication No. 10 2004 052 539.0.

10/589535IAP11 Rec'd PCT/PTO 16 AUG 2006

New PCT National Phase Application Docket No. 32860-001079/US

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	<u>FEES</u>	
	tion Disclosure Statement is being filed concurrently with the filing on; therefore, no fee is required.	f a
the undersigned. I	ner has any questions concerning this IDS, he/she is requested to contait is determined that this IDS has been filed under the wrong rule, to consider this IDS under the proper rule and charge the appropriate fee 08-0750.	the
replies, to charge pa	the Commissioner is hereby authorized in this, concurrent, and futurement or credit any overpayment to Deposit Account No. 08-0750 for a red under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension	ıny
	Respectfully submitted,	
	HARNESS, DICKEY & PIERCE, P.L.C.	
	By: Donald J. Daley, Reg. No. 34,313	
DJD:jap	P.O. Box 8910 Reston, Virginia 20195 (703) 668-8000	
Enclosures:	 ➢ Form PTO-1449(s) ➢ Documents ➢ International Search Report (PCT/ISA/210) ➢ Other: German Translation Aid 	

10/589535 AP11 Rec'd PCT/PTO 16 AUG 26068/08e (05-03)

Approved for use through 04/30/2003: OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO						Complete if Known	
					Application Number	New Application	
	INFO	RMATION	DIS	CLOSURE	Filing Date	August 16,2006	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Klaus Abraham-Fuchs		
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	(use as many shee	ets as	necessary)	Examiner Name	unhavwn	
	Sheet	1	of	1	Attorney Docket Number	32860-001079105	

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No.1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relev Passages or Relevant Figures Appear	
	1	US-6,839,678 B1	01-04-2005	Siemens AG, München DE		
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	0 11.	Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T [®]
Examiner Initials*	Cite No. ¹	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document		
	1	EP 0 936 566 A2	08-18-1999	Siemens AG, München, DE		
	2	DE 101 54 169 A1	05-29-2002	Ford Global Technologies, US		т
	3	WO 01/48676 A1	07-05-2001	Medtronic, US		
	4	WO 03/069431 A2	08-21-2003	Medavante, US		
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Examiner Signature	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to

place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.